K002175

JUL 31 2000

APPENDIX M

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR
POWDER FREE BUBBLE-GUM SCENTED LATEX EXAMINATION GLOVES

Contact person : Cheah Chor Hee

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:
Trade Name – NON-STERILE POWDER FREE BUBBLE-GUM SCENTED LATEX EXAM GLOVES
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I latex patient examination glove 80LYY, powder free and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

Device Description:
Class I latex patient examination gloves 80LYY, powder free and meeting all the requirements of ASTM-D3578-99 Standard Specification for Latex Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Technological Characteristics of Device:

1. Dimension

DIMENSION	ASTM D3578-99	SGMP
X-Small Small Medium Large	70 mm +/- 10 mm 80 mm +/- 10mm 95 mm +/- 10mm 111mm +/- 10mm	70 - 75 mm 80 - 85 mm 90 - 97 mm 105 - 111 mm
Length	230 mm minimum for all sizes	249mm
Thickness - Finger Palm	0.08mm min 0.08mm min	0.08 mm min 0.08 mm min

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2. Physical Properties (ASTM-D3578-99 Standard Specification for Latex Exam Gloves) on Lot# 0015

	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM-D3578-99	SGMP	ASTM-D3578-99	SGMP
	Mpa	Mpa	%	%
Before Aging	14.0		700	
X-Small		23.5		910
Small		27.3		950
Medium		27.8		890
Large		27.1		900
After Aging	14.0		500	
X-Small		24.3		930
Small		25.4		940
Medium		26.8		920
Large		27.1		900

3. Water Tight Test

Using the FDA specified 1,000 ml water leak test, 125 pieces of each size of the gloves were tested and our results are as given below:

BATCH #	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
UN-AGED				
0015	X-Small	125	No	0
0015	Small	125	Yes	1
0015	Medium	125	Yes	2
0015	Large	125	Yes	1
AGED				
0015	X-Small	125	No	0
0015	Small	125	Yes	1
0015	Medium	125	No	0
0015	Large	125	Yes	1

The above figures are within the draft FDA/ASTM D3578-99 requirements for latex exam gloves of 2.5% AQL.

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4. Biocompatibility

The bio-compatibility test results are as per attached in APPENDIX L and show that the gloves passed the tests for examination gloves.

5. Total Residual Powder Content & Presence of Cornstarch

TESTS	FDA INTERNAL REQUIREMENT	SGMP's
Residual Powder Content (ASTM D 6124-97)	2 mg/glove max	Range: 0.7-1.5mg/glove Mean : 1.05 mg/glove
Presence of Cornstarch	Negative	Negative

6. Residual Protein Level

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-95	< 50 µg/g	< 50 µg/g

Conclusion:-

The data presented indicate that the Non-sterile Powder Free Bubble-gum Scented latex examination glove

1. meets/exceeds ASTM- D3578-99 Standard Specifications For Latex Examination Glove,
2. meets FDA pinhole requirements,
3. meets FDA claim criterion of a powder free glove.
4. meets the protein labeling claim level at <50 µg/g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2000

SGMP Company Limited
Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D'emerald
Sparks, Nevada 89434-9550

Re: K002175
Trade Name: Non-Sterile Powder Free Bubble-Gum Scented Latex Examination Glove With Protein Content Labeling Claim (50 micrograms or less)
Regulatory Class: I
Product Code: LYY
Dated: July 13, 2000
Received: July 19, 2000

Dear Ms. Tucker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002175

INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER : K002175

Device Name : Non-sterile Powder Free Latex Examination Gloves with Bubble-gum Scent
With Protein Content Labeling Claim (50 micrograms or less)

Indication For Use :

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002175

Prescription Use ..... **OR** **Over-The-Counter....X.....**
Per 21 CFR 801.109